REMARKS

I. Status of the Claims

Upon entry of the present amendment, claims 2, 4, and 7 are canceled. Claim 1 is amended to recite that the polypeptide comprising an amino acid sequence of SEQ ID NO:1, which finds support in claim 2 as originally filed. Claim 3 is amended to recited that the nucleic acid comprising a nucleotide sequence of SEQ ID NO:2 or 3, which finds support in claim 4 as originally filed. Claim 19 is amended to delete reference to claim 7, now canceled. No new matter is added by the present amendment. Claims 1, 3, 8, 19, and 20 are remain pending.

II. Claim Rejections

A. 35 U.S.C. §101

The Examiner has maintained the rejection of claims 1-4, 7, 8, 19, and 20 under 35 U.S.C. §101 for alleged lack of utility. Applicants respectfully traverse the rejection as it applies to claims 1, 3, 8, 9, 19, and 20 that are currently pending.

In the final Office Action mailed September 16, 2003, the Examiner did not dispute the utility standard under 35 U.S.C. §101 and the case law: once a patent applicant asserts a specific and substantial utility, the Examiner carries the initial burden to show by objective evidence why the asserted utility is not credible. Yet the Examiner contended that because the asserted utility in the present application is neither specific nor substantial, the utility analysis does not reach the step where the Examiner must show why the asserted utility is not credible. Applicants cannot agree.

According to the MPEP §2107.01, a "specific utility" is one that is *specific* to the subject matter claimed, in contrast to a *general* utility that might be applicable to a broad class of the invention. To distinguish a specific utility from a general utility, the MPEP offers several examples, including *Kawai v. Metlesics*, 178 USPQ 158 (CCPA, 1973). In this case, the CCPA held that a statement of a compound having "pharmacological effects on the central nervous system" does not constitute a specific utility, whereas an assertion of "anticonvulsant activity" does. *Id* at 165-166. In the present application, a utility is asserted for treating diseases related

to abnormal olfactory sensory signal transduction and for assaying scents used in food, drug, or cosmetic applications. With respect to identify specific conditions or diseases to be treated, the asserted utility of the present invention more closely resembles the assertion of "anticonvulsant activity" than that of "pharmacological effects on the central nervous system," because convulsion or olfactory sensory perception would involve only certain elements of the "central nervous system." As such, *Kawai v. Metlesics* supports Applicants' position that the asserted utility in the present application does constitute a specific utility.

The MPEP defines a substantial utility as a "real world" use, which is exemplified by methods for treating specified diseases or conditions or methods for identifying compounds useful for such treatment. The asserted utility in the present application includes screening for compounds effective for treating conditions related to altered olfactory signal transduction. In finding this asserted utility short of meeting the requirement for a "real world" use, the Examiner apparently took the position that no substantial utility can be established unless the diseases to be treated are referred to by individual names instead of by their class or type. This is not the requirement set forth by the MPEP or the case law. For example, as mentioned above, an asserted "anticonvulsant activity" was held sufficient to pass the utility requirement in *Kawai v. Metlesics*, even though convulsion can result from various diseases.

Even though the Examiner emphasized in the final Office Action that the asserted utility is neither specific nor substantial, Applicants believe that the real issue in these arguments remains the credibility of the asserted utility, which is based on the biological functions of human CNG2B. For instance, in the third full paragraph on page 3 of the final Office Action, the Examiner pointed to a statement in the specification, "the human CNG2B gene appears to be orthologous to the rat OCNC2 gene, suggesting that it serves a similar functional role," as an indication that significant research is required to determine the specific biological functions of human CNG2B. Applicants do not agree with the Examiner's interpretation.

According to Dr. Zhixin Lin in her Declaration pursuant 37 C.F.R. §1.132 ("the Declaration"), rat OCNC2 encodes a polypeptide that is specifically expressed in the brain and

capable of forming homomultimeric and, with OCNC1 alpha subunits, heteromultimeric cyclic nucleotide gated cation channels involved in olfactory signal transduction. Human CNG2B polypeptide is also highly expressed in the brain, and its amino acid sequence is more than 93% identical to that of rat OCNC2. This high level of sequence identity makes CNG2B the most homologous to rat OCNC2 among all known members of the human CNG family (paragraph 6 of the Declaration). Dr. Lin further states,

> Given such a high level of amino acid sequence homology, one of ordinary skill in the art would believe that the novel human CNG2B gene is the ortholog of rat OCNC2 gene. In other words, a skilled artisan would believe that human CNG2B and rat OCNC2 polypeptides have the same physiological function in mediating olfactory transduction.

Paragraph 7 of the Declaration. It is therefore established that, based on the experimental results disclosed herein (which relate to the expression pattern of the two genes and sequence identity) and without more, a person of skill in the art would already accept human CNG2B as the ortholog of rat OCNC2 and expect the polypeptides encoded by the two genes to have similar if not identical physiological functions.

In contrast to the Declaration, the Examiner showed no scientific evidence or objective reasons why the asserted biological functions of human CNG2B as the ortholog of rat OCNC2 cannot be believed. The Examiner simply dismissed the high levels of similarity in expression pattern and sequence identity between human CNG2B and rat OCNC2 by stating "they are still not the same molecule." This statement reflects more of a personal disbelief than a conclusion based on objective reasoning. Applicants do not believe that the Examiner's approach on this issue is consistent with the standard set forth in the MPEP or the case law.

In summary, Applicants contend that a specific and substantial utility has been asserted in the present application. It is up to the Examiner to make a *prima facie* case why this asserted utility is not credible. As discussed in Applicants' responses to the earlier Office Actions, the Examiner has not made such a *prima facie* showing. Accordingly, Applicants submit that the utility rejection is improper and request its withdrawal.

B. 35 U.S.C. §112, First Paragraph: Enablement

The Examiner also maintained the rejection of claims 1-4, 7, 8, 19, and 20 under 35 U.S.C. §112, first paragraph for alleged lack of enablement. This enablement rejection was based both on the utility rejection as well as on the scope of the claims. Applicants respectfully traverse the rejection in light of the present amendment.

First, as discussed above, the Examiner has not established that the claimed invention lacks utility under 35 U.S.C. §101. Applicants contend that the utility rejection is improper. Hence the enablement rejection on this ground is also improper and should be withdrawn.

Second, the amended claims now recite 100% sequence identity to the amino acid sequence of SEQ ID NO:1 and the nucleotide sequence of SEQ ID NO:2 or 3. The claimed invention is adequately enabled in view of the present disclosure and the technical sophistication in the relevant field of research.

Accordingly, Applicants respectfully request that the Examiner withdraw the enablement rejection based on the scope of the claimed invention.

C. 35 U.S.C. §112, First Paragraph: Written Description

The Examiner further maintained the rejection of claims 1, 3, 7, 19, and 20 under 35 U.S.C. §112, first paragraph, for alleged lack of adequate written description. Specifically, the Examiner alleged that the claimed CNG2B nucleic acids are not properly described due to the recited 90-95% sequence identity to reference sequences. Applicants respectfully request the withdrawal of the rejection in light of the present amendment.

As amended, the pending claims now recite 100% sequence identity to SEQ ID NO:1, 2, or 3. As such, there should be no doubt that the instant application reasonably conveys to one of ordinary skill in the art that the present inventors had in their possession the claimed invention at the time this application was filed.

Accordingly, the withdrawal of the written description rejection is respectfully requested.

D. 35 U.S.C. §102

In addition, the Examiner maintained the rejections of claims 1, 3, 7, 8, 19, and 20 under 35 U.S.C. §102(e) for alleged anticipation by Raumann *et al.* (WO 02/02633, filed June 27, 2001, and claiming priority to US 60/215,391, filed June 29, 2000) and Vernet *et al.* (WO 01/81578, filed April 26, 2001, and claiming priority to US 60/201,474, filed May 3, 2000). Applicants respectfully traversed the rejections in light of the present amendment.

The Examiner indicated in the Office Action mailed April 8, 2003, that Raumann *et al.* disclose a nucleic acid comprising a polynucleotide sequence that is 99.9% identical to SEQ ID NO:3 and encodes an amino acid sequence that is 99.8% identical to SEQ ID NO:1 (the bridging paragraph between pages 9 and 10), and that Vernet *et al.* discloses a nucleic acid comprising a polynucleotide sequence that is 99.9% identical to SEQ ID NO:3 and encodes an amino acid sequence that is 99.8% identical to SEQ ID NO:1 (second full paragraph on page 10). Because the amended claims now recite 100% identity to SEQ ID NO:1, 2, or 3, Raumann *et al.* and Vernet *et al.* cannot anticipate the claims.

Accordingly, the anticipation rejections based on the Raumann *et al.* and Vernet *et al.* references are improper and should be withdrawn.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,

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